

510(K) Summary for Philips PageWriter TC20, 30, 50, 70 Cardiograph

APR - 3 2012

510(k) Summary

ABBREVIATED 510(k) PREMARKET NOTIFICATION

For

Philips Medical Systems

PHILIPS

Philips Electrocardiograph

PageWriter TC20, 30, 50, 70

1. Submitter's Name, Address, Telephone Number:

Name: Philips Medical Systems

Address: 3000 Minuteman Road

Andover, MA 01810, U.S.A.

Phone Number: (978) 659-2404

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The Date the Summary was Prepared:

18 October, 2011

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2. The Name of the Device:

PageWriter TC20/860332 Electrocardiograph

Classification Name: Electrocardiograph.**CFR:** §870.2340**Product Code:** DPS**Class:** II**Panel:** Cardiovascular**3. The identification of the Legally Marketed Device (s) to Which the Submitter Claims Equivalence:**

PageWriter TC30/860306

4. Description of the Device that is the Subject of the 510(k)

The TC series of cardiographs all provide the same basic functionality and utilize the same software code to provide different features. For example the TC 70 cardiograph has a digital patient interface module, the largest display, has the complete set of clinical features and the latest ECG data management capabilities.

The TC 20 cardiograph is the newest addition to the TC family of cardiographs. It provides the following basic feature set for diagnostic cardiographs: 12 lead ECG acquisition and analysis, rhythm printing of ECG, 12 lead ECG report, battery and line operated power, ECG storage and LAN / wireless connectivity.

A detailed comparison with the existing TC 30 cardiograph (predicate device) can be found in section 6 of this 510(K) summary.

New accessories for analog front end:

Item	Part number
PW6L CBL 10-Lead Patient Cable IEC	989803175891
PW6L CBL 10-Lead Patient Cable AHA	989803175901
PW6L CBL Long 10-Lead Patient Cable IEC	989803175911
PW6L CBL Long 10-Lead Patient Cable AHA	989803175921

5. Statement of the Indications for Use of the Device That is the Subject of the 510(k):

To acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes and to record, display, analyze and store these ECG signals for review by the user. To be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated ECG interpretation.

6. Summary of the Technological characteristics of the New Device in Comparison to Those of the Predicate Device

PageWriter TC20 has the same technological characteristics as the predicate device PageWriter TC30.

Following table provides the Technological characteristics of the New Device in Comparison to Those of the Predicate Device.

Feature/ Model	Philips PageWriter TC20 (New Device)	Philips PageWriter TC30 (Predicate) K080999	Comparison

510(K) Summary for Philips PageWriter TC20, 30, 50, 70 Cardiograph

Feature/ Model	Philips PageWriter TC20 (New Device)	Philips PageWriter TC30 (Predicate) K080999	Comparison
Intended use	<p>To acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes and to record, display, analyze and store these ECG signals for review by the user. To be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.</p> <p>The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated ECG interpretation.</p>	<p>To acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes and to record, display, analyze and store these ECG signals for review by the user. To be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.</p> <p>The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated ECG interpretation.</p>	Same
Indications of use	Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.	Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.	Same

510(K) Summary for Philips PageWriter TC20, 30, 50, 70 Cardiograph

Feature/ Model	Philips PageWriter TC20 (New Device)	Philips PageWriter TC30 (Predicate) K080999	Comparison
Power	AC or battery	AC or battery	Same
Battery Chemistry	Lithium Ion battery	Lithium Ion battery (identical battery)	Same
ECG Acquisition	<ul style="list-style-type: none"> AUTO (12 leads) RHYTHM (up to 12 leads) DISCLOSE (1 to 12 leads) 	<ul style="list-style-type: none"> AUTO (12 leads) RHYTHM (up to 12 leads) DISCLOSE (1 to 12 leads) 	same
Keyboard	<ul style="list-style-type: none"> ¾-size qwerty keyboard 	<ul style="list-style-type: none"> ¾-size qwerty keyboard 	same
Touch screen display	<ul style="list-style-type: none"> 640 x 480 pixel resolution 13.3 cm x 9.9 cm (6.5-inch diagonal) color LCD with Touch Screen 	<ul style="list-style-type: none"> 640 x 480 pixel resolution 13.3 cm x 9.9 cm (6.5-inch diagonal) color LCD with Touch Screen 	same
Raw data acquisition	<ul style="list-style-type: none"> 8000 samples per seconds on individual leads for 12 lead ECG 8000 samples per seconds on individual leads for SAEKG 	<ul style="list-style-type: none"> 8000 samples per seconds on individual leads for 12 lead ECG 8000 samples per seconds on individual leads for SAEKG 	same
Sampling rate on cardiograph	<ul style="list-style-type: none"> 500, 1000 and 2000 samples per second per electrode/lead. 12 bit and 16 bit A/D conversion provides 5µV, 2.5µV and 1µV resolution. 	<ul style="list-style-type: none"> 500, 1000 and 2000 samples per second per electrode/lead. 12 bit and 16 bit A/D conversion provides 5µV, 2.5µV and 1µV resolution. 	same
Filters	<ul style="list-style-type: none"> AC noise Baseline wander Artifact 	<ul style="list-style-type: none"> AC noise Baseline wander Artifact 	same
Printer			

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Feature/ Model	Philips PageWriter TC20 (New Device)	Philips PageWriter TC30 (Predicate) K080999	Comparison
Printer resolution	<ul style="list-style-type: none"> High-resolution, digital-array printer using thermal-sensitive paper 200 dpi (voltage axis) by 500 dpi (time axis) 	<ul style="list-style-type: none"> High-resolution, digital-array printer using thermal-sensitive paper 200 dpi (voltage axis) by 500 dpi (time axis) 	same
Battery Operation			
Capacity	<ul style="list-style-type: none"> Typically 50 ECGs and copies on a single charge or 40 minutes of continuous rhythm recording Fully charged 1 battery is to last up to 5 hours under normal usage 	<ul style="list-style-type: none"> Typically 50 ECGs and copies on a single charge or 40 minutes of continuous rhythm recording Fully charged 1 battery is to last up to 5 hours under normal usage 	same
Networking			
Networking connection	<ul style="list-style-type: none"> 10/100 Base-T IEEE 802.3 Ethernet via RJ45 connector (standard) SDIO wireless LAN connection supporting 802.11 b/g standards 	<ul style="list-style-type: none"> 10/100 Base-T IEEE 802.3 Ethernet via RJ45 connector (standard) Compact Flash card wireless LAN connection supporting 802.11 a/b/g standards 	Substantially Equivalent
ECG storage	<ul style="list-style-type: none"> XML File Format (Schema 1.04) Up to 200 ECGs to internal flash memory Up to 200 ECGs per USB Memory Stick 	<ul style="list-style-type: none"> XML File Format (Schema 1.04) Up to 200 ECGs to internal flash memory Up to 200 ECGs per USB Memory Stick 	same
Orders	<ul style="list-style-type: none"> Receive Orders from TraceMaster via the Network Up to 200 Orders stored in internal database 	<ul style="list-style-type: none"> Receive Orders from TraceMaster via the Network Up to 200 Orders stored in internal database 	same
ECG file formats	<ul style="list-style-type: none"> XML (Schema 1.03 and 1.04, 1.04.01, 1.04.02) 	<ul style="list-style-type: none"> XML (Schema 1.03 and 1.04, 1.04.01, 1.04.02) 	same
ECG leads and interpretation			
ECG acquisition	<ul style="list-style-type: none"> 12-Lead ECG acquisition 	<ul style="list-style-type: none"> 12-Lead ECG acquisition 	same

510(K) Summary for Philips PageWriter TC20, 30, 50, 70 Cardiograph

Feature/ Model	Philips PageWriter TC20 (New Device)	Philips PageWriter TC30 (Predicate) K080999	Comparison
Algorithm	• 12-Lead ECG Algorithm	• 12-Lead ECG Algorithm	same
Patient information module (PIM)	No	Yes	See analysis on difference
Patient cable	yes	No	See analysis on difference

Analysis of difference:

For TC20, the ECG circuit is on the main PCA board of the cardiograph; for TC30, the ECG circuit is on the PIM. The TC20 ECG circuit and TC30 PIM have similar basic functions which are to collect the analog signals from the electrode-lead wires, convert the signals to digital signals and send the digital signals to FPGA/processor for processing. The TC30 PIM and TC20 ECG circuit provide isolation between the mains and the patient circuit using the same scientific principles and technical design.

The above table and the analysis demonstrate that the ECG circuit of the TC20 is substantially equivalent with PIM of TC30, from both effectiveness and safety point of view.

Using the FDA "510(k) SUBSTANTIAL EQUIVALENCE DECISION-MAKING PROCESS", we conclude that the new device, Philips PageWriter TC20 w/ A.05 SW, is substantially equivalent with the predicate, Philips PageWriter TC30.

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7. Brief Discussion of the Nonclinical Tests

Tests were conducted to Philips PageWriter TC20 cardiograph and the product meet specific acceptance criteria of the following FDA recognized standards:

Standard number	Description of Standard
AAMI-EC11:1991	Diagnostic Electrocardiographic Device
IEC 60601-1: 1990 +A1 1991+A2 1995	Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995).
IEC 60601-1-2: 2001+A1 2004	Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility Requirements and Tests including Amendment 1: 2004
IEC 60601-2-25: 1993+A1:1999	Medical Electrical Equipment- Part 2: Particular Requirements for Safety and Electrocardiographs

8. Clinical Test

The PageWriter TC20 cardiograph is not required to do clinical test for determination of substantial equivalence. The ECG 12 lead algorithm used for interpretive statements was cleared in a previous 510(K) submittal.

9. Conclusion that PageWriter TC20 is as safe and effective as TC30

The PageWriter TC20 cardiograph has been tested to FDA recognized standards and it complies with the standards. We conclude that TC20 is as safe, as effective, and performs at least as safely and effectively as PageWriter TC30 cardiograph.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

APR - 3 2012

Philips Medical Systems
c/o Ms. Dawn Tibodeau
Senior Reviewer
TUV SUD America, Inc.
1775 Old Highway 8 NW
New Brighton, MN 55112

Re: K113144
Trade/Device Name: Phillips Electrocardiograph, Page Writer TC20
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: March 15, 2012
Received: March 16, 2012

Dear Ms. Tibodeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

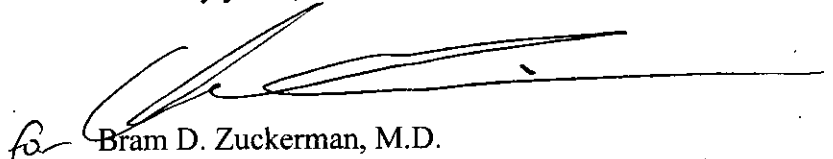
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement510(k) Number: K113144

Device Name: Philips Electrocardiograph, PageWriter TC20 (860332)

To acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes and to record, display, analyze and store these ECG signals for review by the user. To be used in healthcare facilities by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user.

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Prescription X
Use _____
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter
Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113144